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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,727	01/18/2005	Antonio Mete	06275-430US1/100772-1P US	2245
26164	7590	08/24/2007	EXAMINER CHUNG, SUSANNAH LEE	
FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			ART UNIT 1626	
			MAIL DATE 08/24/2007	
			DELIVERY MODE PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/521,727

Applicant(s)

METE ET AL.

Examiner

Susannah Chung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6, and 13-21 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-4, 6, and 13-21 are currently pending in the instant application and are subject to the following new lack of unity requirement. Claims 5 and 7-12 are canceled by preliminary amendment.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 372.

#### ***Lack of Unity Requirement***

Claims 1-4, 6, and 13-21 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1(e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

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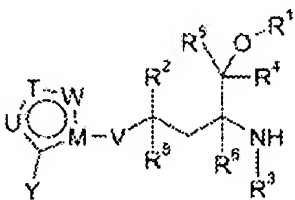
(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

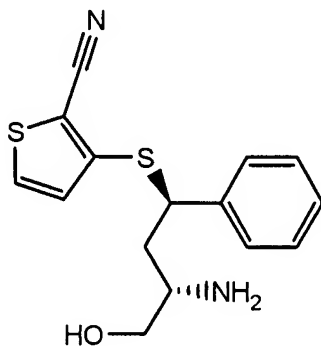
In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. The following groups are exemplary:

Group I: Claims 1-4 and 6 drawn to a compound of formula (I),



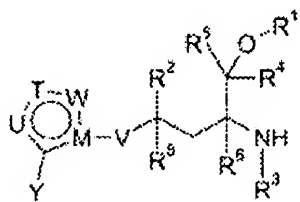
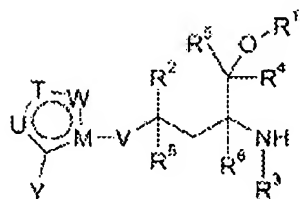
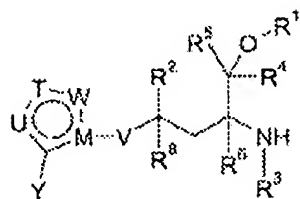
, wherein U is S; T, W, and M are C; Y is CN; V is S; R<sup>1</sup>, R<sup>3</sup>, R<sup>4</sup>,

R<sup>5</sup>, R<sup>6</sup>, R<sup>7</sup> and R<sup>8</sup> are hydrogen; and R<sup>2</sup> is phenyl, yielding the compound of Example 1 of page 17 of the specification, 3-[[[(1R,3S)-3-amino-4-hydroxy-1-phenylbutyl]thio]-2-



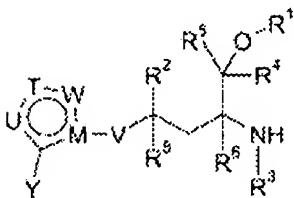
thiophenecarbonitrile,

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Group II: Claims 1-4 and 6 drawn to a compound of formula (I),, wherein **U**, **T**, **W**, and **M** are C; **Y** is CH<sub>3</sub>; **V** is NR<sub>7</sub>; **R1**, **R3**, **R4**,**R5**, **R6**, **R7** and **R8** are hydrogen; and **R2** is methyl.Group III: Claims 1-4 and 6 drawn to a compound of formula (I),, wherein **U** is N; **T**, **W**, and **M** are C; **Y** is CH<sub>3</sub>; **V** is NR<sub>7</sub>; **R1**, **R3**,**R4**, **R5**, **R6**, **R7** and **R8** are hydrogen; and **R2** is methyl.Group IV: Claims 1-4 and 6 drawn to a compound of formula (I),, wherein **U** is O; **T**, **W**, and **M** are C; **Y** is CH<sub>3</sub>; **V** is NR<sub>7</sub>; **R1**, **R3**,**R4**, **R5**, **R6**, **R7** and **R8** are hydrogen; and **R2** is methyl.

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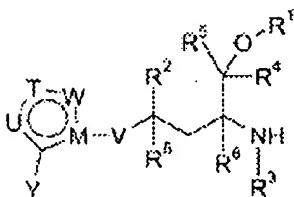
Group V: Claims 1-4 and 6 drawn to a compound of formula (I),



, wherein U is SO; T, W, and M are C; Y is CH<sub>3</sub>; V is NR<sub>7</sub>; R<sub>1</sub>, R<sub>3</sub>,

R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub>, R<sub>7</sub> and R<sub>8</sub> are hydrogen; and R<sub>2</sub> is methyl.

Group VI: Claims 1-4 and 6 drawn to a compound of formula (I),



, wherein U is SO<sub>2</sub>; T, W, and M are C; Y is CH<sub>3</sub>; V is NR<sub>7</sub>; R<sub>1</sub>, R<sub>3</sub>,

R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub>, R<sub>7</sub> and R<sub>8</sub> are hydrogen; and R<sub>2</sub> is methyl.

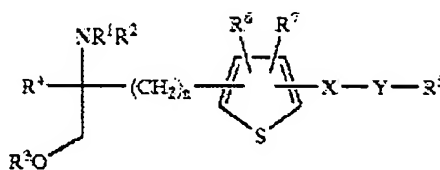
Group VII: Claims 13-16 and 18-21 drawn to a method of using the compound of formula (I), wherein the disorder to be treated is pain.

Group VIII: Claim 17 drawn to a process for the preparation of a compound of formula (I).

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: they do not share the same essential structural element(s) that define the “special technical feature” necessary to specify a contribution over the prior art.

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There is no significant structural moiety common to Groups I-VIII, which is not known in the art and would make a contribution over the prior art. Note that the compound of formula (I) contains numerous variables making a core structure difficult to ascertain. If an attempt at a core structure were to be made, it would consist of an alkyl chain substituted with a nitrogen, oxygen, and cyclic moiety. This is well known in the art. (See Nishi et al., U.S. Pat. No.



6,723,745, wherein the compound of formula (I), , consists of the alkyl chain, substituted with a nitrogen, oxygen and cyclic moiety. In addition, there are numerous substituents and various combinations that could be made from the generic compound of formula (I). Also, the various process claims all require different reactants and/or reagents and/or reaction conditions and/or products. Thus, these claims lack the corresponding special technical feature(s) necessary to link them together to fulfill the lack of unity invention requirement.

Therefore since the claims are drawn to more than a product and more than a process, the claims lack unity of invention and should be limited to only one product and one process of making that product.

A telephone call was made to Attorney Robert Nabinger on 08/20/2007 to request an oral election to the above restriction requirement, but did not result in an election being made.

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*Telephone Inquiry*

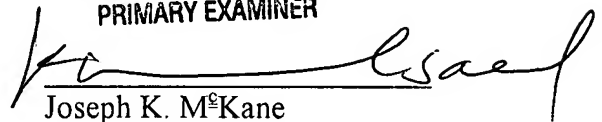
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER



Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

Date: 20 August 2007